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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/589,924

08/18/2006

Franz Xaver Schwarz

33660-US-PCT

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11/25/2009

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EXAMINER

AHMED, HASAN SYED

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

11/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/589,924 | Applicant(s) SCHWARZ, FRANZ XAVER | |
| | Examiner HASAN S. AHMED | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 14-26 and 32-34 is/are pending in the application.
- 4a) Of the above claim(s) 14-26 and 32-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/18/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's: (a) response to restriction requirement and amendment, filed on 4 September 2009; and (b) transmittal letter, statement under 37 CFR 3.73(b), and PTO/SB/81, all filed on 9 September 2009.

* * * * *

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 4 September 2009 is acknowledged. The traversal is on the ground that a serious burden does not exist in examining all of the claims together. This is not found persuasive because elements exist in each of the groups which require searches in areas not required for the other groups.

The requirement is still deemed proper and is therefore made FINAL.

Claims 14-26 and 32-34 (as numbered in the amendment filed on 4 September 2009) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4 September 2009.

* * * * *

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

* * * * *

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-10 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 080 862 (“Grimmett”) (cited in the IDS filed on 18 August 2006).

Grimmett discloses water-dispersible extruded granules comprising amoxicillin trihydrate and sugar (see e.g. page 1, line 14; claim 1). The granules are prepared by, “...bringing into association the components [of the granule] and thereafter extruding the blended mixture.” See page 3, lines 2-6. The amoxicillin trihydrate and sugar, *inter alia*, are passed through a screen then extruded with an aqueous solution (dichloromethane) (reading on example 1) (see example 1). The extruded product is collected and passed through a screen and dried (reading on example 1) (see example 1). The dried extrudate is then blended with 5% SYLOID (reading on the homogenization of claim 1(e)) (see example 1). The granulate may be dissolved in water to form a syrup (reading on the suspension of claim 1(f)) (see page 3, lines 18-19). Sugar is the common word for sucrose, as such, the sugar disclosed by Grimmett is deemed to be functionally equivalent to the sucrose of instant claims 2, 3, and 8. Amoxycillin trihydrate concentration is disclosed as, e.g., 13.65% (reading on the ranges recited in instant claims 5-7) (see example 1). Sugar (sucrose) concentration is disclosed as,

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e.g., 68.9% (see example 1). The granulate particle size is disclosed as 1000 micrometers (see example 1) (reading on claims 9 and 10).

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 080 862 ("Grimmett") in view of U.S. 2002/0006433 ("Davidson") (cited in the IDS filed on 18 August 2006).

Grimmett is discussed above. Grimmett explains that the disclosed composition is beneficial the treatment of bacterial infections (see page 1, line 3). Grimmett differs from the instant application in that it does not teach the sugar alcohol of instant claim 4. However, granulate compositions comprising amoxicillin trihydrate and mannitol were known in the art at the time the instant application was filed, as evinced by Davidson (see, e.g., p. [0021]). Davidson explains that mannitol is beneficial as a chewable base (see, e.g., p. [0006]).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a method of making a granulate comprising amoxicillin trihydrate and mannitol, as taught by Grimmett in view of Davidson. One of ordinary skill in the art at the time the invention was made would have been motivated to use

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mannitol because it is beneficial as a chewable base, as explained by Davidson (see above).

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615